Attacks on Dr. Hartman's "expectations" theory and/or damages methodology

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS	Judge Patti B. Saris

MERITS REPORT AND DECLARATION OF GREGORY K. BELL, Ph.D., ON BEHALF OF TRACK 1 DEFENDANTS

March 22, 2006

incentive to lower pharmaceutical prices to preferred physician providers, leading to an increase in healthcare costs.

19. In addition to my disagreement with the expectations theory advanced by Plaintiffs' expert, Dr. Hartman, I find the following specific faults in his liability and damages analysis. I conclude that Dr. Hartman's methodology inappropriately finds liability where none may exist and results in inflated estimates of alleged damages.

19.1. Dr. Hartman commits four types of errors when calculating "spread." First, Dr. Hartman fails to calculate the Hartman ASPs appropriately by including in his calculations the effect of sales to classes of trade that are not at issue in the litigation. Second, Dr. Hartman fails to consider variation in AWP. For instance, to the extent that the AWP differs among the pricing publications, the determination of alleged liability and damages can depend upon the pricing publication chosen for the AWP. Third, Dr. Hartman makes no attempt to assess the extent to which reimbursement rates would increase for related services and administration fees if the reimbursement rate for PADs were to decline. Fourth, with respect to Medicare Part B, Classes 1 and 2, Dr. Hartman incorrectly assumes that reimbursement was always intended to be equal to acquisition cost.

19.2. Dr. Hartman also fails to properly confine his analyses to the classes at issue. Adjustments must be made to account for product sales that are excluded by the class definition, reimbursements by TPPs that were aware of pharmaceutical pricing behavior based on their actual purchase or contracting for pharmaceuticals, and speculation with respect to missing data.

III. THE HARTMAN EXPECTATIONS METHODOLOGY

20. To identify alleged instances of liability, Dr. Hartman proposes an expectations-based methodology. Dr. Hartman maintains that payors expected there to be a

"reasonably predictable" relationship between the AWP for a drug and its acquisition cost. Dr. Hartman opines that a "conservative" assumption of the expected difference between AWP and acquisition cost is 30 percent of the Hartman ASP and accordingly concludes on liability in those instances where the difference between AWP and the Hartman ASP is greater than 30 percent of the Hartman ASP.[28]

21. I am not aware of any deposition testimony, documents produced in this case, or other information that would suggest that payors held any such expectations. In fact, Dr. Hartman was unable to identify a third party payor that expected AWP to exceed ASP by less than 30 percent.[29] Further, I am not aware that Congress determined the reimbursement rates for Medicare Part B drugs based on such expectations nor that private payors negotiated with physician practices to reimburse for PADs based on such expectations. It is my opinion that the expectations methodology as advanced by Dr. Hartman is inconsistent with the information on acquisition costs that was available to payors; is inconsistent with the economics of the pharmaceutical industry, in particular the product lifecycle; and is inconsistent with the objectives that payors maintained for the reimbursement rates set for PADs. It is also my opinion that a remedy of increased transparency regarding price concessions on PADs, as apparently advocated by Dr. Hartman,[30] would be contrary to the public interest, likely leading to an increase in healthcare costs.

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28 Hartman Liability Report, ¶ 59 (e). Dr. Hartman reports "spread" values as the difference between AWP and Hartman ASP as a percentage of ASP (i.e., "spread" = (AWP – Hartman ASP) / Hartman ASP). Most publicly available literature, including that relied upon by Dr. Hartman, reports pharmaceutical pricing terms as a percentage of AWP (i.e., discount = (AWP – ASP) / AWP). As a result of this reporting difference, Dr. Hartman's "spread" of 30 percent based on ASP is equivalent to 23 percent based on AWP. Consistent with the relevant literature and industry convention, I report price concession values in terms of AWP. See also Deposition of Raymond S. Hartman, February 27 through March 1, 2006 ("Hartman Liability Deposition"), p. 1255.

29 Hartman Liability Deposition, p. 787.

30 Hartman Liability Report, footnote 63.

A. Information available

22. Dr. Hartman does not explain how payors developed their expectations, if any, regarding the differences between AWP and acquisition cost. In his September 3, 2004 declaration ("Hartman Class Declaration"), Dr. Hartman concluded that surveys by the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("DHHS") over the period 1984–2002 are examples of information that would be sufficient to summarize the market's understanding of the relationship between AWP and acquisition costs for the purposes of calculating "yardstick" spreads, and that these estimates could be further refined with manufacturers' data and depositions of TPPs and managed care organizations.[31] The Hartman Liability Report chooses three PADs that were "successful 'break-through' innovator drugs [to] serve as reasonable yardsticks for 'but-for' spreads" and, "as a cross-check," Dr. Hartman reviews "a variety of publicly-available survey research" ostensibly summarizing the "market" expectations of spreads.[32]

23. In this review of publicly available survey research, Dr. Hartman principally cites a 1992 study from the OIG on the relationship between acquisition costs and AWPs for chemotherapy drugs. Dr. Hartman ignores the OIG findings that manufacturer price concessions on single-source drugs (20 percent discount) were lower and less variable than price concessions on multi-source drugs (20 to 83 percent discounts).[33] Furthermore, using Plaintiffs' definition of spreads, the

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31 Hartman Class Declaration, 2004, ¶ 29.

32 Hartman Liability Report, ¶ 22 and ¶ 59 (a). I note that Dr. Hartman calculates his "yardstick spreads" for the three products (Blenoxane, Taxol, and Zofran) by considering only the period during which the products were not subject to generic competition.

33 See OIG November 1992, Appendix III. Dr. Hartman's use of single-source information alone is also inconsistent with his class certification analysis, where he initially noted that an expectations model should have a different yardstick for single- and multi-source drugs (Hartman Class Declaration, 2004, ¶ 19). In liability analysis, Dr. Hartman rejected the necessity of multi-source information: "there are several multi-source drugs where that relationship deviates from what I am talking about here, but I have focused this on single-source drugs, since that has been the focus of much of the damage period in many of the drugs." (Hartman Liability Deposition, p. 730).

study announced that "spreads" were as high as 488 percent for these chemotherapy drugs.[34]

24. Plaintiffs' theory of liability is predicated on the assumptions that AWP was the only price "signal" publicly available to payors and that payors were unable to obtain information on the price concessions that certain providers obtained.[35] However, by acknowledging that publicly-available survey research informed "market expectations," Dr. Hartman has acknowledged that payors had access to, and apparently used, information regarding the relationships between physician acquisition costs and AWPs.[36] This acknowledgement regarding available information is fundamentally irreconcilable with an economic theory of fraud.

25. Perhaps most damaging to Dr. Hartman's expectations theory, however, is one of the OIG's main findings in the study: "There is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of the physician's acquisition cost ...."[37] This finding is diametrically opposed to Dr. Hartman's theory that payors expected a "reasonably predictable" relationship between AWP and acquisition cost.

26. Nonetheless, Dr. Hartman concludes that "[t]here is no evidence that the yardsticks for TPP price expectations for multi-source physician-administered drugs were any different from those for singe-source [sic] physician-administered drugs"[38] and "There is no survey information of which I am aware that has documented spreads on generic physician-administered pharmaceuticals."[39] Both of these conclusions are clearly refuted by the very study that he references, let

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34 The reported discounts of 20 and 83 percent correspond to "spread" values of 25 and 488 percent, respectively. As defined in footnote 28, "spread" = (AWP – ASP) / ASP, so "spread" = 0.83 / (1 – 0.83) = 488.2 percent.

35 Hartman Class Rebuttal, 2004, ¶ 15 (f) (i).

36 Hartman Class Declaration, 2004, ¶¶ 30–31; Hartman Liability Deposition, p. 731. Dr. Rosenthal also agrees that payors had access to, and apparently used, information regarding the relationships between physician acquisition costs and AWPs. (See Deposition of Meredith Rosenthal, February 22-23, 2006 ("Rosenthal Liability Deposition"), pp. 55–57.)

37 OIG November 1992, Appendix II.

38 Hartman Liability Report, ¶ 60 (f).

39 Hartman Liability Report, footnote 63.

alone being refuted by several other studies that were performed and became publicly-available during the class period.

27. Exhibit C summarizes the pharmaceutical price concessions documented in 31 studies available between 1984 and 2004 that commented on pharmaceutical acquisition cost, AWP, and reimbursement rates.[40] Not all studies considered both single- and multi-source drugs, nor did every study consider SADs and PADs. However, considering each drug in each study, there are more than 1,000 examples of pharmaceutical price concessions in general, as well as how specific circumstances (e.g., therapeutic or generic competition, drug type) affect price concessions.

28. This summary of publicly-available information demonstrates two key points. First, there is substantial variation in the reported price concessions. Second, the price concessions frequently exceed the 30 percent "spread" liability threshold advocated by Dr. Hartman. I find that the publicly-reported distribution of acquisition costs for single-source PADs ranged from 53 percent of AWP to 87 percent of AWP;[41] I find that the acquisition costs for multi-source PADs ranged from 15 percent of AWP to 84 percent of AWP.[42] In my opinion, such information does not give rise to a set of expectations that there would be a "reasonably predictable" relationship between the AWP for a drug and its acquisition cost. Further, such information does not give rise to expectations that the differences between AWP and acquisition costs would not be expected to exceed 30 percent of the Hartman ASP. For instance, the difference between acquisition cost and AWP for single-source PADs ranged from 15 percent of acquisition cost (10th percentile) to 88 percent of acquisition cost (90th percentile);

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40 Exhibit C reports the price concessions both in terms of discounts (i.e., as a percentage of AWP) and "spreads" (i.e., as a percentage of ASP). So, for example, the 30.4 percent discount for the 25th percentile of the multi-source PADs corresponds to a 43.7 percent "spread."

41 Calculated as 100 percent less the discount reported in Exhibit C.

42 These values are based on the 10th and 90th percentiles of discounts as a percentage of AWP that are reported in Exhibit C. (The 10th percentile means that only 10 percent of the observations are at or below this level of price concession; similarly, the 90th percentile means that 90 percent of the observations are at or below this level of price concession.)

for multi-source PADs the difference ranged from 18 percent (10th percentile) of acquisition cost to 586 percent (90th percentile) of acquisition cost.

29. Based on the information presented in Exhibit C, a payor forming expectations regarding the relationship between AWP and acquisition costs would not reach the conclusion claimed by Dr. Hartman. Instead, such a payor would realize at least three points related to acquisition cost. First, the price concessions offered by drug vary substantially. Second, 30 percent of ASP is not a reasonable expectation of the possible difference between acquisition cost and AWP, even for a single-source PAD.[43] As demonstrated by the statistics in Exhibit C, a "spread" value that characterized at least 75 percent of the single-source PAD observations would need to be at least 41.7 percent. Third, the price concessions increase substantially, in both level and variation, as competition increases and a measurement based on single-source products would not be expected to apply to multi-source products.[44]

30. In addition to the government-produced information regarding pharmaceutical prices and the Medicare and Medicaid programs, other government programs provided additional information to payors and other industry participants regarding the existence and potential magnitude of price concessions. The schedule of prices and contracts for supplies and services frequently purchased by the federal government (and select other public agencies) is known as the Federal Supply Schedule ("FSS"). The Veteran's Administration ("VA") negotiates FSS prices for pharmaceuticals with manufacturers. Admittedly, the VA has an important lever in this negotiation—in addition to the volume of purchases

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[43] In addition to ignoring publicly-available studies, Dr. Hartman's theory also ignores available information conveyed by other pricing terms. For example, despite recognizing a "formulaic" relationship between AWP and wholesale acquisition cost ("WAC") in which AWP is often 20 to 25 percent greater than WAC, Dr. Hartman does not consider how payor expectations would change for a drug that did not display these characteristics. (Hartman Liability Deposition, pp. 676-677).

[44] Note that the variation in price concessions across the product lifecycle, as noted in the OIG November 1992 study, demonstrates that the benchmark PADs selected by Dr. Hartman cannot characterize the "expected" difference between acquisition cost and AWP, even if such a concept existed.

represented by those agencies authorized to purchase from the FSS, Medicaid sales for *any* of a manufacturer's products require that *all* of that manufacturer's products be included in the FSS program.[45] As a result, the VA has been able to negotiate prices that are estimated at 52 percent of AWP, or about 15 percent less than the Medicaid rebate program's best price.[46]

31. The FSS prices that result from these negotiations are publicly available and include both SADs and PADs.[47] For example, the 2005 FSS price of $161.05 for Zoladex, a PAD for prostate cancer marketed by AstraZeneca, represents a 68 percent discount on the AWP of $469.99.[48] As a result, since at least 1993, payors and other industry participants were able to observe the price a major purchaser of pharmaceuticals was able to negotiate with manufacturers. While other purchasers were not eligible for these prices, they would know that they could not expect to negotiate lower prices than the FSS, making these prices the 'floor' for acquisition costs. For more on different publicly available price schedules, see Exhibit D.

B. Product lifecycle and the economics of the pharmaceutical industry

32. Dr. Hartman's expectations approach does not comport with the economics of the industry. Dr. Hartman's expectations theory implies that payors expected the difference between AWP and physician acquisition cost would not exceed 30 percent of the Hartman ASP, that payors expected this relationship to hold across

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45 Under Section 603 of the Veterans Health Care Act of 1992, manufacturers are required to list all of their brand name drugs on the FSS as a condition of having their drugs covered and reimbursed by the Medicaid program. See William H. von Oehsen, III, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Public Health Institute, May 2001, p. 15.

46 Congressional Budget Office ("CBO"), Prices for Brand-Name Drugs Under Selected Federal Programs, June 2005. The Medicaid Best Price is defined as the greater of a 15.1 percent reduction in the average manufacturer price ("AMP") of a pharmaceutical or the best price provided by a pharmaceutical manufacturer to a commercial payor (adjusted for inflation). The Medicaid Best Price is not publicly available.

47 Pharmacy Benefits Management, Strategic Healthcare Group, U.S. Department of Veterans Affairs, Drug and Pharmaceutical Prices, http://www.pbm.va.gov/PBM/prices.htm (accessed February 23, 2006).

48 Based on 3.6 mg injectable Safesystem Syringe, NDC 00310-0950-36, http://www.pbm.va.gov/PBM/prices.htm (accessed March 1, 2006); Red Book, 2005 Edition, Thomson Micromedex, p. 670.

time and across drugs, and that payors determined physician reimbursement rates based on their understanding of the relationship between AWP and physician acquisition costs. Yet, nowhere does Dr. Hartman address the economics of the industry and the rational expectation of the emergence of price competition during a product's lifecycle as it is exposed to therapeutic and generic substitution.

33. Branded pharmaceutical manufacturers set the list price for a product at launch, based on the product's relative clinical attributes, market research, and other commercial conditions. Over time, these list prices tend to increase, often reflecting a growing baseline of use, the arrival of new indications, and the price of competing products. As Dr. Hartman points out, manufacturers of brand name pharmaceuticals that face neither therapeutic nor generic competition have no incentive to offer significant price concessions on their products.[49] Nonetheless, some price concessions may be offered to certain preferred purchasers, such as a prestigious teaching hospital in order to help establish the product in the prescribing habits of new physicians. Then, as competition evolves, other products may be launched. Due to patent protection, these products would not be the same chemical entity, but they may be part of the same broad category of compounds and act as possible therapeutic substitutes. As a result, one would expect the pharmaceutical manufacturers to engage in price competition to become the preferred product for preferred purchasers. In general, this competition does not manifest as a decrease in price to all purchasers, but as a decrease in price to preferred purchasers. Thus, these price concessions could vary by purchaser, for instance larger purchasers might be able to negotiate lower prices. Accordingly, one could certainly observe a general increase in the price of a product to all purchasers at the same time as there is a decrease in the net price to one or more preferred purchasers. Finally, net price competition could become even more intense with the launch of generic versions of the product. Some purchasers may continue to pay the price for the branded version of the product; other purchasers may shop around for the lowest acquisition cost.

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[49] See Hartman Liability Report, ¶¶ 58-59; and Hartman Class Rebuttal, ¶ 19.

34. In my opinion, payors expected price concessions to vary across the lifecycle by product and by purchaser. Not only is this a standard expectation of business, but such competition was the foundation for the pricing behavior observed for SADs as payors established formularies, negotiated with manufacturers for rebates based on formulary position, and instituted maximum allowable cost ("MAC") policies once generics were available.[50] For example, when the Health Care Financing Administration ("HCFA", the predecessor to the Centers for Medicare and Medicaid Services ("CMS"), the regulatory body that administers the Medicare program) began to implement the Outpatient Prospective Payment System ("OPPS"), it determined acquisition costs for a number of "transitional pass-through" drugs, estimating that average price concessions increased from 32 to 39 percent of AWP when a single-source drug encountered therapeutic competition, and increased from 39 to 57 percent of AWP when drugs encountered generic competition.[51] In terms of the metrics employed by Dr. Hartman, price concessions of 32 to 39 percent correspond to "spreads" of 47 to 64 percent, while price concessions of 39 to 57 percent correspond to "spreads" of 64 to 133 percent. In fact, there is a wealth of government and academic literature devoted to demonstrating the existence, potential values, and rate of change for pharmaceutical price concessions due to changing competitive circumstances.[52]

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50 As an example with respect to PADs, I note that in 2000, Florida added 400 NDCs for injectable drug products to its state MAC price listing. (The Florida Senate, *Review of Medicaid Prescription Drug Pricing*, Interim Project Report 2005-141, November 2004, p. 5.) Other states such as Montana and Wisconsin have also included PADs in their MAC lists. (Administrative Rules of Montana, Department of Public Health and Human Services, Section 37.86.105(4) available at http://arm.sos.state.mt.us/37/37-19835.htm; Wisconsin Department of Health and Family Services, Budget Change Items, p. 244, available at http://www.pswi.org/government/Fiscal%20Bureau%20Budget%20Analysis.pdf.)

51 Health Care Financing Administration, "Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services," 65 FR 18434, April 7, 2000 at 65 FR 18481.

52 For government publications reporting changes in price concessions over the product lifecycle, see, for example, OIG November 1992, pp. 6-7, Appendix III. For a survey of academic literature evaluating the effects of therapeutic or generic competition, see, for example, Sara Fisher Ellison, "What Prices Can Tell Us About the Market for Antibiotics," MIT working paper, July 1998 and Don-Churl Suh, Willard G. Manning, Jr., Stephen Schondelmeyer, and Ronald Hadsall, "Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry," Health Services Research 35:2 (June 2000). Note that the studies upon which Dr. Hartman relies to justify his benchmark approach to damages (Hartman Class Declaration,

C. Payors accept reimbursement rates in excess of acquisition cost

35. Dr. Hartman assumes that payors determine reimbursements based on an expected relationship between acquisition cost and AWP, while ignoring other economic factors affecting reimbursement.[53] On the contrary, payors had incentives to shift patient care from the higher-cost setting of the hospital to the lower-cost setting of the physician office reward physicians, payors needed to motivate physicians to participate in their networks, and payors needed to reimburse for un- or under-reimbursed services that were ancillary to the use of PADs.

i. Site of care

36. Payors, however, have strong incentives to shift patient care out of the hospital and into physicians' offices in order to reduce the total cost of care. Cancer care by dedicated and specialized staff using streamlined office-based practices is considered to be more efficient and cost-effective than cancer care in the hospital setting.[54] One oncologist was quoted as saying that "[t]he biggest difference is in efficiency…the same treatment that lasts three hours in the community [cancer center] will take three to four times longer in the hospital."[55] According to Gary Owens, the Vice President Medical Management and Policy at Independence Blue Cross, it costs less to have a drug administered in the physician's office than in a hospital setting.[56] The cost-effectiveness of outpatient care relative to inpatient hospital care has been recognized by Medicare and managed care organizations, which have generally encouraged substitution of outpatient services, including drug therapies, for inpatient care.[57] For example, insurers

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footnote 24) apply benchmarks to characterize the price competition that results from generic entry.

53 See, for example, Hartman Liability Deposition, pp. 825, 855, 860, and 864.

54 Herzlinger, Regina E., Cancer Care in America, Description and Implications of Outpatient Community-Based Cancer Care, Boston Healthcare Associates, Inc., 2002 ("Herzlinger 2002"), p. 13. See also Deposition of Jill Herbold, CIGNA, January 14, 2005 ("Herbold (CIGNA) Deposition"), p. 76.

55 Herzlinger, 2002, p. 13, quoting "an oncologist from South Carolina."

56 Deposition of Gary Owens, Independence Blue Cross ("IBC"), July 22, 2005 ("Owens (IBC) Deposition"), pp. 127–128.

57 See Joshua P. Cohen, "PBMs and a Medicare Prescription Drug Benefit," *Food and Drug Law Journal*, Vol. 55, 2000, p. 312 and Patricia M. Danzon and Mark V. Pauly, Health Insurance and

recognize that Remicade therapy provided in the physician office is significantly less expensive than Remicade therapy provided in a hospital, and as a consequence have been willing to pay physicians a substantial administration fee. Some private insurers have assigned higher copayments to cancer care delivered in the hospital setting to extend this cost incentive to patients.[58]

37. "Improvements in oncology patient care, including new and more effective chemotherapy and adjuvant therapies and improved symptom management, have evolved over the past 25 years."[59] New chemotherapies have shorter infusion times, allowing infusion to be completed during an outpatient visit.[60] Additionally, as supportive care agents such as the anti-anemia products (Procrit and Aranesp) and anti-emetics (Anzemet, Kytril, Zofran) have reduced the toxic side effects of chemotherapy, it has become easier to treat patients in a community setting, allowing patients to receive treatment close to home rather than having to travel to major medical centers or specialty cancer hospitals to receive treatment.[61] The consequent increased access to care in outpatient community cancer practices reduces the burden of treatment on patients, caregivers, and family members, especially for patients in rural areas.[62] As a result, whereas most chemotherapy was administered in a hospital setting as recently as the late 1980s, the "Centers for Disease Control and Prevention (CDC) data currently [as of 2003] indicate that more than 80 percent of all chemotherapy

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the Growth in Pharmaceutical Expenditures, *Journal of Law and Economics*, Vol. XLV, October 2002, pp. 587–613 at 606–607. See also Barton C. McCann and Julia A. James, *The Impact of Medicare Payment Policies on Patient Access to Quality Cancer Care*, Health Policy Alternatives, Washington, D.C., June 1999 ("McCann and James 1999"), p. 4.

58 Herzlinger 2002, p. 16.

59 Siegel, Jerry, "Back to the Future: An Oncology Case Study," Pharmaceutical Reimbursement: Keeping Up with Changing Times, Proceedings of an educational symposium during the 39th ASHP Midyear Clinic Meeting, December 5, 2004 ("Siegel 2004"), www.ashpadvantage.com/website_images/pdf/reimburse.pdf, p. 15 (accessed September 16, 2005).

60 Herzlinger 2002, p. 3.

61 Siegel 2004, p. 15.

62 Siegel 2004, p. 17.

treatment encounters occur in non-hospital outpatient settings (freestanding oncology physicians' offices and community cancer centers)."[63]

38. Further, it has been known throughout the alleged damages periods that reimbursement rates can encourage physicians to shift care to outpatient settings. For example, in 1992 the General Accounting Office ("GAO") released a study of Medicare chemotherapy reimbursement in inpatient and outpatient settings. It found that the amount that oncologists were reimbursed by Medicare could affect the treatment setting and therefore the total costs to Medicare for the patient's care.[64] A similar relationship between reimbursement rates and the physician's choice of site of care has been observed for private payors.[65]

39. Despite acknowledged incentives to shift care out of the hospital, if physicians are not adequately compensated for specific PADs and associated costs (e.g., cancer treatment), they may cease treating these patients in their offices, forcing the patients back to hospital settings.[66] For example, 34 percent of health plans surveyed in 2004 reported increasing non-drug reimbursements to physicians to compensate for lost revenue associated with pharmaceutical reimbursement.[67]

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63 Oncology Nursing Society, Reimbursement vs. Reality: A Discussion Paper on Medicare Payments for Cancer Treatment, 2003 ("ONS 2003"), p. 1, http://www.ons.org/lac/pdf/Reimbursement.pdf. See, also, Herzlinger 2002, p. 8. Community-based cancer care has also increased patients' access to clinical trials for novel treatments. (Herzlinger 2002, p. 14.)

64 GAO, *Medicare: Reimbursement Policies Can Influence the Setting and Cost of Chemotherapy*, GAO/PEMD-92-98, July 1992 ("GAO 1992"), pp. 1-5. See also McCann and James 1999, p. 4.

65 Groves, Anita, "The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Changes in the Outpatient Prospective Payment System: Assessing the Impact on Your Health System," *Pharmaceutical Reimbursement: Keeping Up with Changing Times*, Proceedings of an educational symposium during the 39th ASHP Midyear Clinical Meeting, December 5, 2004 ("Groves 2004"), accessed at http://www.ashpadvantage.com/website_images/pdf/reimburse.pdf, p. 6.

66 A report produced for the Medicare Payment Advisory Commission ("MedPAC") provides an example: "In one case, physicians closed down their office-based practices for three months and shifted treatment to the hospital outpatient department. This raised the cost of a chemotherapy session from $3,000 to $5,000." See "Physician-Administered Drugs: Distribution and Payment Issues in the Private Sector; A study conducted by NORC at the University of Chicago and Georgetown University for the Medicare Payment Advisory Commission," August 2003 ("NORC Report 2003"), p. 18.

67 Baker, Thomas, "Specialty Therapies Lose Special Status," *Pharmaceutical Executive*, September 1, 2004 ("Baker 2004"), accessed at http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=123007.

Oncologists and rheumatologists faced with the loss of pharmaceutical reimbursement through use of specialty pharmacy programs have opted for alternate therapies, changed the site of care, or, in the case of rheumatologists, abandoned physician-administered therapies (like J&J's Remicade) in favor of self-administered therapies (such as Enbrel (Immunex Corporation) and Humira (Abbott Laboratories)).[68]

40. Recent changes in reimbursement[69] illustrate the regression of outpatient care into the hospital due to reduced payments to physicians: short-stay oncology admissions at Cedars-Sinai Medical Center and the nationwide experience with immune globulin infusion patients.

40.1. A recent analysis of short-stay oncology admissions at Cedars-Sinai Medical Center in Los Angeles suggests that a shift in site of care from the physician clinic to the hospital is already occurring. The analysis found "a trend in which if an oncologist's office did not obtain favorable reimbursement terms from a managed care contract, then the office-based patient was admitted to the hospital for treatment."[70] There is also concern that such a shift may lead to overcrowding in hospitals. In fact, the pharmacists at Cedars-Sinai spoke with the doctors who were admitting patients for chemotherapy and asked them to stop doing so, in order to "ensure that beds remain available for acutely ill patients."[71]

40.2. Patients receiving immune globulin infusions to prevent life-threatening infections have been forced to seek care in hospitals rather than treatment in physicians' offices in response to lower Medicare reimbursement rates

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68 Baker 2004.

69 These changes refer to the shift to ASP-based reimbursement as a result of Medicare reforms in 2003, a topic discussed in the next section.

70 Shane, Rita, "A Proactive Approach to MMA: Improving Outpatient Revenue Cycle Management," *Pharmaceutical Reimbursement: Keeping Up with Changing Times*, Proceedings of an educational symposium during the 39th ASHP Midyear Clinical Meeting, December 5, 2004 ("Shane 2004"), p. 10, accessed at http://www.ashpadvantage.com/website_images/pdf/reimburse.pdf.

71 Shane 2004, p. 10.

to physicians. Under ASP-based reimbursement, Medicare reduced reimbursement rates to physicians for the drug from $66 per gram to $39 per gram in powder form and $56 per gram for liquid form, while hospitals are reimbursed for the drug at $80 per gram. According to the largest distributor of the drug, the cheapest powdered brands cost $44 per gram and can reach prices of $90 per gram, making it cost-ineffective for physicians to administer the drug in their offices and forcing patients into hospitals.[72] This reimbursement reduction has had numerous negative effects: it has decreased access to care, increased total costs of treatment, and put patients at risk.[73] For many patients, treatment has been delayed or refused by hospitals that reportedly lack adequate treatment facilities or supplies of the drug.[74] The Immune Deficiency Foundation, in response to this crisis, suggested that a solution would be for immune globulin to be treated like a blood product, in which case its reimbursement would "revert to the traditional Average Wholesale Price (AWP) methodology."[75]

II. PAD reimbursement and cross-subsidization of physician services

41. The gross revenues associated with PADs must cover a variety of expenses specifically associated with the drug: acquisition cost, inventory management and temperature-controlled storage, hazardous waste disposal, and wastage, among others.[76] Drug administration and preparation (often requiring special procedures

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72 Neergaard, Lauran, "HEALTHBEAT: Patients Scramble for Lifesaving Drug in Wake of Medicare Payment Change," *Associated Press*, June 13, 2005 (BC Cycle).

73 "Healthcare Crisis Hits Medicare Patients Needing Immune Globulin—Medicare Modernization Act has unintended but devastating repercussions for seriously ill beneficiaries," Immune Deficiency Foundation Media Release, May 16, 2005 ("IDF 2005"), p. 1, accessed at www.primaryimmune.org/media/releases/IVIGMedRel-Testimonials-Fact%20Sheet.pdf.

74 IDF 2005, p. 3.

75 IDF 2005, p. 4.

76 Community Oncology Alliance ("COA"), The Cancer Care Comprehensive Coding Task Force, Recommendations on the Reimbursement of Cancer Care Services Provided to Medicare (Part B) Recipients in Community Cancer Practices, June 2, 2004 ("COA 2004a"), pp. 10-12; COA, Cancer Care Comprehensive Coding Task Force, Overview Report on Coding Costs (CPEP), 2004 ("COA, 2004b"); "ANCO Responds to Slanted NY Times Article About Drug Reimbursement

for toxic chemotherapeutics) expenses have generally been characterized as being inadequately reimbursed, with these expenses cross-subsidized by the difference between the drug's acquisition cost and its reimbursed amount.[77] Thus, when payors introduce reforms that reduce reimbursement for PADs, they generally must also make other changes in reimbursement for services to compensate fairly physicians.[78]

42. Other services that the physician might provide, including cancer treatment planning and cancer therapy management, are not separately coded for reimbursement.[79] In addition, there are the unreimbursed supportive services that form the backbone of oncology care, including patient nutrition counseling, psycho/social counseling services, family education, and financial counseling.[80] These are all services deemed to be essential for safe and effective cancer care.[81] Then there are all of the practice expenses that must be covered. These include the costs of pre-certifying the use of chemotherapy drugs with payors, appointment scheduling, follow-up on missed appointments, claims submission, billing and collecting co-payments from patients, and indirect office expenses (e.g., rent, utilities, supplies).[82] Reimbursement for these services and expenses must come from the reimbursement for those services that are specifically

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and Cancer Doctors," January 28, 2003 ("ANCO 2003"), accessed at http://www.californiaoncology.org/assns/ancoresp12603.htm.

77 See McCann and James 1999, pp. 1, 4, and discussion by Joan Sokolovsky, MedPAC, at the MedPAC 2003 Public Meeting, March 21, 2003 ("MedPAC 2003 Public Meeting"), p. 4.

78 This is precisely what CMS did when Medicare Part B moved to an ASP-based reimbursement and the potential for the Competitive Acquisition Program ("CAP") was introduced, as I discuss below. Private payors also considered how to change administration fees if reimbursements fell as a result of converting to an ASP-based reimbursement system. See Deposition of Joe Spahn, Senior Health Care Consultant, Anthem BCBS, November 30, 2004 ("Spahn (Anthem BCBS) Deposition"), pp. 107-109.

79 COA 2004a, p. 10.

80 McCann and James 1999, p. 1; "MCOs Oncology Strategies Focus on Provider Issues," *Specialty Pharmacy News*, April 2005; Dawn Gencarelli, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?" *NHPF Issue Brief*, No. 775, June 7, 2002 ("Gencarelli 2002"), p. 5; COA 2004a, pp. 9-11.

81 COA 2004a, pp. 10-13.

82 COA 2004a, p. 13.

indicated or through the cross-subsidization that is provided by the difference between the acquisition cost and reimbursement for the oncolytics.[83]

43. As such, the difference between the physician's reimbursement for a PAD and the acquisition cost is not simply "pocketed" as profit. Further, for many practices, this difference on oncology drugs is part of what enables the practice to offer quality care to those not able to pay.[84] For example, many Medicare patients do not have supplemental insurance and it can be difficult for oncology practices to collect patient co-payments. Thus, when treating these patients the practices may receive only gross revenues for 80 percent of the Medicare reimbursement rate.[85] For instance, the Community Oncology Alliance ("COA") completed a survey in 2004 that found that 25.3 percent of Medicare patient co-payments are uncollectible and written off as bad debt.[86] According to the Medical Group Management Association ("MGMA"), the typical physician office experiences a non-collection rate equivalent to 7.5 percent of allowable reimbursement.[87]

44. For years, oncologists have expressed concerns that service reimbursement rates from Medicare and private payors are insufficient to cover the costs of care.[88] After it became evident in the mid-1980s that the more cost-effective and patient-friendly approach to chemotherapy was administration in freestanding facilities as compared to hospitals, Congress requested a study on possible Medicare reimbursement changes to more accurately reflect the costs associated

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83 See also Northwest Georgia Oncology Centers Video, February 2005, accessed at http://www.communityoncology.org.

84 Note that some patients are able to access the drug manufacturers' compassionate care programs to pay for their oncology products. For example, GlaxoSmithKline announced in 2001 that it was creating a national discount program for low-income elderly people without prescription drug coverage. ("GlaxoSmithKline Plans Drug Discount Program for Low-Income Elderly," *YourHealthDaily*, October 3, 2001.) Other compassionate care programs include RX Outreach; developed by Express Scripts Specialty Distribution Services for those under the Federal Poverty Level, and the Merck Prescription Discount Program, developed for all uninsured patients. ("Health Care Program—Resources on Pharmaceutical Costs and Access," 2005 Edition, National Conference of State Legislatures, December 20, 2005.)

85 COA 2004a, p. 17.

86 COA, "A Letter to Mark B. McClellan," December 7, 2004 ("COA 2004c"), p. 5.

87 ONS 2003, p. 4.

88 McCann and James, 1999, p. 1.

with providing chemotherapy in physicians' offices.[89] In 1988, HCFA recognized that payment for the administration of chemotherapy may be inadequate.[90] HCFA also responded directly to the concerns of oncologists in the *Federal Register* on November 25, 1992, stating: "We were also persuaded by the data we received during the comment period that the practice expense RVUs do not adequately cover the cost of supplies for these services."[91] The Medicare Payment Advisory Commission also acknowledged that the Medicare physician fee schedule rates for drug administration may be too low, particularly for chemotherapy.[92]

45. A 1999 study estimated the profitability of a seven-physician oncology practice under various Medicare reimbursement scenarios.[93] The study found that if drugs had been reimbursed at AWP, the practice would have earned an estimated $149,865 annually on Medicare business, which amounts to $21,409 on average per physician and $166 per Medicare patient. If reimbursement rates were reduced to 95 percent of AWP the practice would lose an estimated $162,058, or $23,151 per physician and $180 per Medicare patient. A proposal at that time to reduce reimbursement rates to 83 percent of AWP would have resulted in estimated losses of $910,680, or $130,097 per physician and $1,010 per patient. The key finding of the study is that surpluses generated by drug reimbursement levels at the time (i.e., AWP minus 5 percent) were not sufficient to overcome the underpayment for professional services, resulting in a net loss on Medicare business.[94]

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89 ONS 2003, p. 1.

90 53 FR 39644, October 11, 1988.

91 57 FR 55914, November 25, 1992.

92 MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2003 ("MedPAC March 2003"), pp. 157–159.

93 McCann and James, 1999, pp. 13–17.

94 McCann and James, 1999, pp. 2-3, 16. See also Gemma M. Tarlach, "Domino Effect: Will new rule drive patients from doctors to hospitals?" *Drug Topics*, April 6, 1998, p. 29 (1).

D. Increased transparency would not be efficient or in the public interest

46. One logical implication of Dr. Hartman's theory is that Plaintiffs would have been better off had there been no uncertainty regarding the acquisition costs for PADs. In my opinion, Plaintiffs would not have been better off. Economic literature recognizes that price concessions are more likely when other purchasers are unaware of the concessions.[95] If manufacturers were forced to disclose price concessions, then the incentives to provide such concessions would be reduced—the cost of providing a price concession to one buyer is increased if that concession becomes shared with all buyers. As a result, greater transparency could be expected to lead to greater reluctance on the part of pharmaceutical manufacturers to offer price concessions leading to an increase in the healthcare costs, not a decrease.[96] As one payor noted at a public hearing conducted by the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"), "We believe that price competition can best be achieved when negotiated prices and rebates are kept confidential. Widespread public disclosure of prices is unnecessary to assure that the ultimate payer receives most of the benefit of drug rebate arrangements."[97] In fact, as government regulatory agencies charged with protecting competition and consumer welfare, the FTC and DOJ issued a joint report in which they recognized that market competition, rather than regulation, is more likely to arrive at "an optimal level of transparency."[98] Considering that the

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95 "There is a long tradition in economics suggesting that in such environments, 'the best deals are secret deals.'" Expert Report of Professor Ernst R. Berndt to Judge Patti B. Saris, MDL No. 1456, Civil Action No 01-12257-PBS, United States District Court of Massachusetts, February 9, 2005 ("Berndt Report"), ¶ 166.

96 See, for example: MedPAC, *Report to the Congress: Variation and Innovation in Medicare*, June 2003 ("MedPAC June 2003"), p. 161 (Medicare context); Letter from FTC to Assembly Member Greg Aghazarian, September 7, 2004 (PBM context); and Daniel P. O'Brien and Greg Shaffer, "The Welfare Effects of Forbidding Discriminatory Discounts: A Secondary Line Analysis of Robinson-Patman," *Journal of Law, Economics, & Organization*, Vol. 10, No. 2, pp. 296-318 (theoretical context).

97 Anthony Barrueta, Senior Counsel for the Kaiser Foundation Health Plan, FTC/DOJ Joint Hearings, Health Care and Competition Law and Policy, Pharmacy Benefit Management Companies (PBMs), June 26, 2003.

98 In the context of SADs and PBMs, the FTC and DOJ noted: "Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. ... Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages

provision of health insurance is traditionally considered to be a competitive market,[99] such increases in costs to insurers would ultimately result in higher costs to plan sponsors and employers.

47. This fact was illustrated by the implementation of the Medicaid Best Price and rebate regulations. Notably, government research indicated that a principal effect of the Medicaid Best Price provisions introduced in the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") was to increase costs as a result of reduced price concessions. Manufacturers could no longer offer a large discount to a single customer without incurring the costs of extending the discount to all purchasers under the Medicaid program. For example, a 1991 GAO study found increases in prescription drug prices paid by the VA and the Department of Defense ("DOD") after the enactment of OBRA 90.[100] As a result of these findings, Congress passed the Medicaid Drug Rebate Amendments in 1992, amending the OBRA 90 rebate provisions to exclude prices charged under the FSS in the calculation of the Medicaid Best Price.[101] According to the CBO, the number of single-source drugs with a best price discount as high as 50 percent fell from nearly one-third in 1991 to nine percent in 1994, and the average best price discount declined from more than 36 percent to 20 percent over the same period.[102]

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disclosure of the information health plan sponsors require to decide on the PBM with which to contract." FTC and DOJ, "Improving Health Care: A Dose of Competition," July 2004 ("Dose of Competition"), Chapter 7, p. 17.

99 The FTC and DOJ hosted a series of hearings on competition in health care services in 2002 and 2003, noting that, "Many hearing participants testified that health insurance markets in most geographic areas enjoy robust competition, with 'multiple health insurer competitors and several product options, including HMO, PPO, POS, and consumer directed health plans.'" (Dose of Competition, Chapter 6, p. 7, quoting Fred Dodson, Vice President, Network Management, PacifiCare of California (Appendix A, p. A-8).)

100 GAO, *Medicaid: Changes in Drug Prices Paid by VA and DOD Since the Enactment of Rebate Provisions*, GAO/HRD-91-139, September 1991, pp. 1-2.

101 Medicaid Drug Rebate Amendments of 1992 (House Report 102-384 (II)), September 22, 1992, p. 8.

102 CBO, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, January 1996, pp. ix, 28. The 9, 20, 36, and 50 percent discounts correspond to "spreads" of 10, 25, 56, and 100 percent, respectively.

48. Further, there is already research recognizing that reimbursements based on Medicare's publicly-available ASPs is expected to lead to higher prices, by eliminating some price concessions.[103] Thomas Scully, former CMS Administrator, anticipated in 2005 that the ASP system would put inflationary pressure on pricing by creating an incentive for sponsors to set prices as high as possible.[104]

49. The most telling reference of the effect of additional transparency, however, might come from CMS itself. As part of the MMA, the Competitive Acquisition Program provided an alternative to the traditional "buy-and-bill" responsibilities for physicians, where physicians can choose to obtain a PAD from the CAP in return for administration fees rather than purchasing the PAD and being reimbursed based on ASP plus six percent. Pharmaceutical manufacturers would compete (through a bidding process) for their drugs' inclusion in the CAP program. An early issue in the implementation of the CAP program was whether CAP sales should be included in the manufacturers' ASP calculations. Under an interim final rule issued November 21, 2005, CMS noted:

> "We find good cause to waive the requirement for publication of a notice of proposed rulemaking and public comment on the grounds that it is contrary to the public interest. We have re-examined our statutory authority and have determined that both the CAP and ASP payment methodologies are best served by excluding units supplied under the CAP from the calculation of ASP for an initial period of 3 years. We believe that excluding CAP drug units from the ASP calculation will give manufacturers an incentive to provide discounts to approved CAP vendors that will, in turn, result in lower prices under the CAP."[105]

50. As indicated by this decision, CMS explicitly recognizes that the ASP-based reimbursement method could be expected to constrain the price concessions that pharmaceutical manufacturers might otherwise grant. CMS's requirement that

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103 Danzon, Patricia M., Gail R. Wilensky, and Kathleen E. Means, "Alternative Strategies for Medicare Payment of Outpatient Prescription Drugs–Part B and Beyond," *American Journal of Managed Care*, March 2005, p. 179.

104 "Average Sales Price Creates Inflationary Pressure, Former CMS Head Says," *The Pink Sheet*, June 27, 2005, p. 25.

105 70 FR 70480, November 21, 2005.

pharmaceutical manufacturers use data provided by CAP vendors for the purposes of excluding CAP sales in ASP calculations has also been cited as a disincentive to discounting.[106]

51. Thus, there is a compelling public interest in maintaining the current levels of price transparency in the pharmaceutical reimbursement system. Increasing price transparency might also reduce price differentials across classes of trade, contrary to the decision in *In Re: Brand Name Prescription Drugs* that there is a compelling economic reason for allowing variation in prices across different classes of trade.[107] If these price differentials were eliminated, then certain market segments would see increased prices, which might preclude access to treatment.

E. Conclusion

52. Dr. Hartman's expectations theory thus fails to consider the following:

52.1. Payors have access to a wealth of information about the difference between acquisition cost and AWP.

52.2. Payors expect that the difference between acquisition cost and AWP would vary by drug and over time, depending on competitive circumstances.

52.3. Payors intended reimbursement rates to exceed acquisition costs in order to provide and maintain incentives for care to be administered as appropriate in the physician's office as compared to the hospital.

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106 Pharmaceutical Research and Manufacturers Association ("PhRMA"), a trade group for innovator pharmaceutical manufacturers, has noted that this CMS requirement may "discourage manufacturer discounts because prices would be included in the ASP if drugs sold to CAP vendors are not administered ultimately to a beneficiary by a participating physician." ("Streamlined Method for Exempting CAP Drugs From ASP Urged by PhRMA, BIO," *The Pink Sheet*, February 20, 2006, p. 24.) See also "End of Aranesp, Procrit Pricing War Illustrates Inflationary Impact of ASP," *The Pink Sheet*, February 13, 2006, p. 11.

107 "In re Brand Name Prescription Drugs Antitrust Litigation," The United States Court of Appeals for the Seventh Circuit, MDL No. 997, Argued June 25, 1997, Decided August 15, 1997, Opinion Authored by Chief Judge Posner.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris **FILED UNDER SEAL**

EXPERT REPORT OF JANUSZ A. ORDOVER

the differences between acquisition costs and AWPs and to more effectively negotiate reimbursement terms with physicians or physician groups.[23]

29. Of course I am not arguing, or even suggesting, that information on transaction spreads is perfect, ubiquitous, or disseminated immediately. However, the available evidence makes clear that there are many sources of qualitative and quantitative information regarding these spreads, which leads me to reasonably conclude that Medicare and TPPs alike were not (and should not have been) operating under the mistaken premise that AWP invariably represents a reliable predictor of acquisition costs.[24] Thus, as I explain in greater detail in the next section, in their negotiations with physicians, Medicare and TPPs would have -- or should have -- used whatever knowledge they had to control the margins between the reimbursed amounts and physicians' acquisition costs, taking into account the constraint that physicians require a certain margin on PADs (and other services) in order to earn an acceptable rate of return on their practices.

C. Pharmaceutical Industry Economics

30. Dr. Hartman's analysis of permissible spreads (or spreads that would arise in his but-for world) is also marred by his implausibly constricted view of what constitutes a permissible differential or spread between AWP (which I assume *arguendo* is the reimbursed amount) and acquisition costs. He takes the position that any differential above his promulgated threshold evidences fraudulent behavior and a lack of information by the payors and thus concludes that any differential in excess of 30% must stem from unlawful conduct aimed at defrauding payors. Similarly, Dr. Rosenthal interprets Dr. Hartman's "yardstick" as indicating that any amount of spread above 30%

[23] *See Id.* and the Appendix for examples of TPPs that employ individuals with experience in the provider community.

[24] In this context it is important to point out that from the perspective of the payor it is not important whether AWP is equal to AC but, rather whether there is a reasonably predictable relationship between AWP and the acquisition cost for a given drug or category of drugs.

is attributable to the "alleged fraud" while any amount up to 30% is the product of "[physician] market power, [and] other factors."[25] This is incorrect economics. It is obvious that the non-fraudulent spread can vary over time for any number of legitimate reasons that have nothing to do with the purported scheme to mislead or defraud Medicare and TPPs.

31. The opinions of Drs. Hartman and Rosenthal lead to an untenable conclusion that legitimate competition among drug manufacturers would be deemed fraudulent if it led to lower acquisition costs for PADs while resulting in a differential between acquisition costs and AWP exceeding 30%.[26] For example, if a pharmaceutical company, to better reflect competitive realities, offered discounts to physicians sufficient to create a differential between acquisition costs and AWP of 35% while holding the AWP unchanged, this conduct would be deemed unlawful by Drs. Hartman and Rosenthal.[27] In fact, their characterization of competitive spreads would condemn a drug company whose pricing behavior created a spread exceeding the 30% benchmark, even in the case where the spread resulted from a competition-driven reduction in acquisition costs that was intended to induce TPPs to promote the usage of the drug in physicians' offices. A finding of liability in this situation makes no economic sense: on the contrary, such pricing behavior creates desirable incentives to promote the drug to patients and to reduce healthcare system costs. Drs. Hartman and Rosenthal appear to reject a reasonable economic proposition that a higher available margin resulting from a reduction in acquisition costs will

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[25] *See* Rosenthal Deposition at pp. 321-322.

[26] This point is also developed in Professor Scott-Morton's Report (*see* pp. 16, 28-29, and 32) and in Professor McFadden's Report (*see* Declaration of Daniel L. McFadden ("McFadden Report"), pp. 3-4).

[27] Indeed, Dr. Hartman's view seems to be that pharmaceutical manufacturers can legitimately compete on spread so long as that competition does not become so aggressive that the spread exceeds 30%. Dr. Hartman states that, "They're still competing on spread, but they're doing it within the bounds that are subject to my – to my legal threshold." (*See* Hartman Deposition at p. 1231.) I am aware of no economic principle that would condemn firms' behavior according to the test offered by Dr. Hartman.

eventually be eroded by payors in the negotiations over reimbursement rates.[28]

32. To better understand the economic factors underlying drug manufacturers' observed pricing behavior, it is useful to start with the simple example of a cereal manufacturer who wants to increase its market share. To meet this objective, the manufacturer may provide incentive payments to supermarkets while holding the wholesale price constant. The expectation is that competition among supermarkets will lead to a reduction in the retail price of the cereal, stimulate sales, and benefit consumers. Two aspects of this example are worth noting. First, the manufacturers' incentive payments initially cause a change in the spread between the retail price and the wholesale price. And second, consumers end up paying lower prices irrespective of whether they have any information about the supermarkets' net acquisition costs. Competition among grocery retailers operates to maintain a reasonable spread between prices at retail and supermarkets' net acquisition costs.

33. In the case of prescription drugs, the situation is more complex because consumers only pay a fraction (possibly zero) of the total charge for a drug while other payors cover the difference.[29] Hence, competitive forces operate in a more indirect fashion. In particular, to ensure that margins do not get out of line relative to the amounts doctors seek to earn from their practices, the marketplace relies upon competition among doctors for access to plan members and competition among payors to build and maintain attractive networks of providers while controlling the costs of operating the plans. Just as in the cereal example above, effective competition in the

[28] Persistence of a higher margin following an increase in the spread may reflect higher costs associated with the administration of the drug to the patients or other changes in the economics of medical practices.

[29] Patients can pay either a fixed amount per prescription or a fixed percentage of the cost of the prescription. In either case, they do not immediately bear the full costs of a price increase or obtain a full benefit from a price decrease.

prescription drug marketplace does not mean that the "wholesale" margins remain static or always at or below some maximum arbitrary permissible threshold. More to the point raised by the instant litigation is the fact that in the context of physician-administered drugs, manufacturers do not have access to the same share-shifting strategies as their cereal counterparts. A cereal manufacturer, in addition to offering incentive payments to grocery retailers, can lower wholesale prices and depend upon competition among retailers to pass along to consumers the benefits of lower wholesale prices which, in turn, would shift share toward the less expensive cereal.

34. For physician-administered drugs, however, such a strategy will not necessarily be effective in inducing additional sales. Because physician reimbursement is often based upon some level of discount off of AWP, a reduction in AWP likely would not benefit doctors relative to the spreads received on competing drugs. Thus, a reduction in AWP could potentially lead some doctors to shift away from the manufacturer's drug, all else being equal, as opposed to increase their usage of the drug.

35. Another potentially perverse consequence of the economic reasoning advanced by Plaintiffs and Dr. Hartman is that if information regarding manufacturers' discounting practices were instantaneously transmitted to payors this likely would lessen incentives to reduce acquisition costs to physicians and thus would tend to deprive consumers of the benefits of lower drug acquisition costs to the administering doctors. In fact, if disclosure of an increased spread (*i.e.*, higher discount) to Medicare or TPP is very quick, and the payors use that information to lower reimbursement rates to the doctors and/or force rival suppliers to make similar concessions very quickly, a manufacturer who lowers the ASP would achieve no lead time over its rivals and would thus garner little if any competitive advantage by offering the discounts in the first place. Indeed, payors' insistence on lower reimbursement rates would lessen the physicians' incentive to shift share and thus undermine the whole strategy. Simply stated, the discounting strategy would cease to provide an effective means of shifting

share, and hence manufacturers likely would scale back substantially the pricing incentives offered to physicians.[30] Insofar as such incentives ultimately lead to lower reimbursement rates, the attendant benefits to TPPs and consumers would be lost.

36. Building on their flawed assumption that drug manufacturers' pricing strategies are substantially opaque, Plaintiffs and Dr. Hartman contend that the putative fraudulent scheme caused payors to "substantially overpay" for certain drugs,[31] *i.e.*, to negotiate reimbursement rates that exceeded those that would have obtained in the assumed but-for world of pricing transparency. Conspicuously absent from Dr. Hartman's analysis is any economic assessment of how competition among payors to attract physicians to their networks and competition among physicians to attract patients to their practices would affect reimbursement rates negotiated between the two parties. Indeed, the methodology adopted by Dr. Hartman to derive the caps on non-fraudulent levels of the spread actively prevents him from factoring these market realities into his analysis. Moreover, in my understanding, his methodology leads him to assume that any amount of imperfect information[32] in the marketplace will lead to distorted outcomes, even if the competitive forces bearing on payors and physicians are operating well. Contrary to Dr. Hartman, it is my view that irrespective of the spread initially established by the manufacturer, even if the participants in the marketplace do not possess perfect information regarding the spreads, forces of competition will ultimately work to adjust reimbursement rates or

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[30] Dr. Rosenthal acknowledged at her deposition that "there can be cases in which keeping discounts secret has economic benefits." (*See* Rosenthal Deposition at pp. 389-391.)

[31] *See, e.g.*, Amended Master Consolidated Class Action Complaint Modified Per The Court's Instruction At The November 21, 2003 Hearing With Amgen Amendments, at p. 34.

[32] While the evidence convincingly demonstrates that payors were aware of the differentials between AWP and provider acquisition costs, it is not my position that the dissemination of pricing information is in any way instantaneous. However, the existence of lags in the flow of information does not negate my overall conclusion that the competitive forces facing physicians and payors will eventually push reimbursement rates, and hence, consumers' expenditures as well, to levels consistent with the earnings required by doctors to sustain their practices.

overall returns on the practice, thereby bringing the costs of the health plans to the insureds to the level consistent with competition among drug companies, health plans, and physicians: that is to competitive levels.

37. The analytical flaw in Dr. Hartman's report which I discussed in the preceding paragraphs is also highlighted by Dr. Berndt in his report to Judge Saris. Dr. Berndt identifies a number of legitimate economic factors that influence the pricing behavior of drug manufacturers – and thus the spreads – including the drug's therapeutic class, the number of single-source, brand-name competing drugs in the same therapeutic class, whether any brands in the same therapeutic class are multi-source, and the time before the expected patent expiration and initial generic entry.[33] Consistent with my critique of Dr. Hartman, Dr. Berndt aptly summarizes the challenge facing Dr. Hartman's simplistic model of permissible spreads:

> "How can it be determined that at any given point in time, it is one or more of the above factors that affected and were largely responsible for the price decisions made by defendant manufacturers during the product's life cycle, rather than Defendants' alleged AWP scheme to collect inflated prescription drug payments? Simply examining and recording larger differences in percent 'spreads' between each AWPID drug and 'drugs not subject to this Litigation' will not be sufficient to establish reliably that any differential 'spread' is attributable solely, partly or not at all to the alleged AWP scheme to collect inflated prescription drug payments."[34]

IV. PLAINTIFFS' LIABILITY THEORY IS NOT APPLICABLE TO REMICADE

A. Introduction

38. In this section I examine the application and relevance of the Plaintiffs' theory of harm to Remicade (infliximab). I understand that Remicade is an

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[33] *See* Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, February 9, 2005, at p. 115.

[34] *Id.* p. 116.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO CV-12257-PBS AND 01-CV-339	)	Chief Magistrate Judge Marianne B. Bowler

DECLARATION OF JOHN P. GOULD

MARCH 22, 2006

on the functioning of competitive markets for several reasons. First, it could deter sellers from offering selective discounts (often a major factor in the functioning of competitive markets), because any discount offered to one customer could then "spill over" to other customer groups, where the seller would stand to lose more revenue than it gained in the market where it wanted to discount. Second, it could limit a seller's scope for negotiations with different customer groups. Third, it could make it more difficult or costly to raise prices at a later time, when costs or competitive conditions have changed.

41. Thus, there are valid strategic and business reasons why firms do not want to reduce WAC for existing products. These reasons have nothing to do with the claims of fraud advanced by Plaintiffs.

42. The Plaintiffs' experts' description of the but-for world fixes the spread between ASP and AWP at no greater than 30 percent of ASP. Equivalently, in this but-for world, AstraZeneca would be liable for damages if it offered customers discounts from WAC greater than 3.84 percent. The absurdity of this blatantly anticompetitive restriction is clear when contemplating how this restriction would be applied to other industries.

VII. PLAINTIFFS FAIL TO CONSIDER CHANGES IN THE BUT-FOR WORLD IF SPREADS HAD BEEN CONSTRAINED

43. In their analysis, Plaintiffs focus solely on the spread between AWP and the ASP that their economist calculates, holding constant everything else.. This unrealistic approach introduces a substantial error into Plaintiffs' analysis of impact and damages. In particular, Professor Hartman calculates damages assuming that (a)

total sales of each drug would be the same in the but-for world; (b) ASP (and, presumably, the price at which each individual customer purchased) would be the same in the but-for world and (c) reimbursement arrangements of Medicare, TPPs and patients would be the same in the but-for world. Thus, Plaintiffs and Professor Hartman calculate damages by assuming that the only difference between the actual and but-for worlds is that AWP would be lower in this but-for world by an amount required to make the "but-for" spread equal to the percentage that Dr. Hartman claims is appropriate.

44. As I now explain, for several reasons, the assumption that all else remains constant in the but-for world is inconsistent with both economic theory and empirical evidence regarding the market for Zoladex.

A. IN THE BUT-FOR WORLD THERE WOULD HAVE BEEN MORE SALES OF LUPRON, A HIGHER PRICED PRODUCT

45. The history of competition in supply of LHRH agonists that I presented above shows that when it was launched Zoladex faced competition from Lupron, another LHRH agonist. Throughout the class period, as shown in Figure 1, Zoladex had a lower WAC and AWP than did Lupron.[18] If Zoladex sales were lower in the but-for world than in the actual world, more sales would have occurred at higher prices to the extent that providers administered Lupron rather than Zoladex. For patients who, in the but-for world, were administered Lupron instead of Zoladex, co-payments would have been higher (20 percent of a higher AWP), increasing (not lowering) the amount paid by the Class members responsible for those

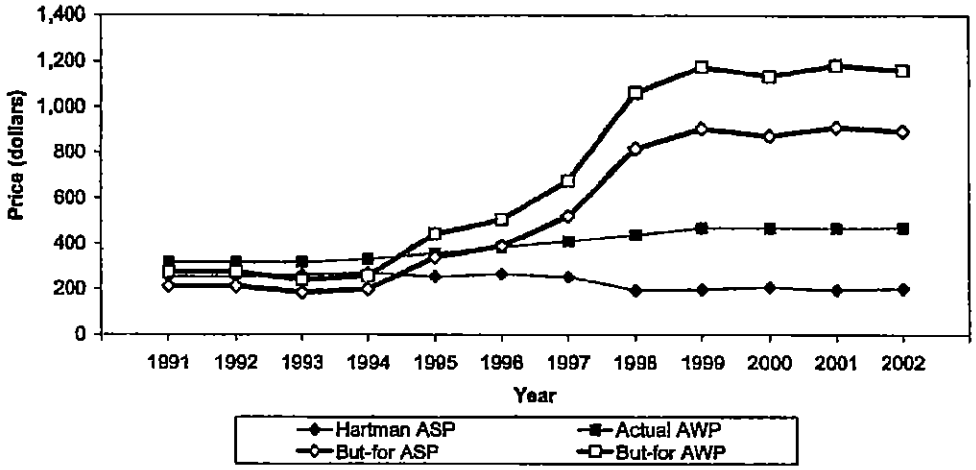
[18] In the discussion that follows I assume that Lupron's conduct – pricing and other marketing – remains unchanged from the historical experience.

copays. As I noted in paragraph 14, in 2003, the Medicare Reimbursement Amount for Lupron exceeded that for Zoladex by $165 per one-month dose, or by 37 percent. Class members' copay amounts would have been higher by the same percentage.

B. ASTRAZENECA AND OTHER FIRMS WOULD HAVE AN INCENTIVE TO REDUCE DISCOUNTS AND RAISE ACQUISITION PRICES TO ACHIEVE A GIVEN PERCENTAGE SPREAD

46. Dr. Hartman claims that any spread greater than 30 percent is fraudulent, because payers expected (and therefore bargained as if) that were the actual provider spread. Assume that the actual spread had been limited to 30 percent (i.e., to a 3.84 percent discount from WAC). A manufacturer like AstraZeneca could satisfy this standard and yet still give providers the same dollar spread by reducing discounts and raising both acquisition prices and WAC. In 1998, for example, the average dollar spread (based on Dr. Hartman's measure of Zoladex ASP) was $223.57, while the percentage spread was 119 percent (given AWP of $411.57). (See Figure 4.) If, instead, AstraZeneca's ASP for Zoladex had been $745.24 and it had set a WAC of $775 (resulting in AWP of $969), then the percentage spread would have satisfied Dr. Hartman's claimed maximum of 30 percent (($969-$745.24)/$745.24=30 percent and S969-$745=$224). According to Dr. Hartman's logic, there would have been no fraud in this case. With this pricing, AstraZeneca still would be giving providers the same dollar incentive to prescribe Zoladex as they have today.

Figure 4
Comparison of Hartman But-For World and Alternative But-For World for Zoladex
(NDC 310096036, 3.6 mg)



Source: Hartman's 2/3/2006 Addendum.

47. In this "non-fraudulent" world, the parties who would be worse off would be payers (Class members) – the parties that Dr. Hartman claims he is trying to protect from fraud. The hypothetical but-for world of higher WAC and higher acquisition prices and the same dollar and percentage spreads generates no damages according to Dr. Hartman. Yet, clearly it is much worse for payers (Medicare, TPPs and individuals) than is the actual world. Thus, if the spread were limited by fiat, economic theory suggests that the result would be higher AWPs, less discounting and higher acquisition prices, so that manufacturers could continue to give providers competitive incentives to prescribe their drugs.

48. It is clear from this analysis that Dr. Hartman does not consider or address the complexities of the "but-for" world.[19] Rather, he makes a number of (tacit)

[19] In his deposition, Dr. Hartman confirms that he has not considered these critical issues:
"Q: But the providers' market power is a constant, right? It will remain the same irrespective of the reimbursement formula that is used?
A: I haven't – I haven't done an analysis. I can't render an opinion on that." (Feb. 27, 2006, p. 864.)

assumptions that have the effect of distorting and substantially overstating his estimate of damages. Indeed, one could extend the last example by having the spread greater than $223.57, thereby further raising the cost to payers.

49. Because Dr. Hartman does not even acknowledge the issues raised by the more complex and realistic recognition of the dynamics of the "but for" world, we do not know how he would address the issues raised here. He might argue that it would not be possible to raise the price of Zoladex above the current level—though nothing in his model or analysis explains why this might the case. Actually, under his unrealistic assumption that payers are substantially uninformed about prices, it is possible that a higher price than we now see might indeed arise in a situation where a 30 percent spread is imposed in the "but for" world.

50. To show more of the complexities that would arise in the (realistic) "but-for" world that Hartman ignores, suppose that for some reason the current Zoladex WAC (and thus AWP) cannot increase but also that the spread cannot be more than 30 percent. These conditions do not change the competitive conditions of the market and the significant role that urologists play in choices of therapeutic procedure (Lupron, Zoladex, surgery). Dr. Hartman claims that urologists have "market power" to determine the choice of therapy and the power to "shift patients" between therapies.[20] In this circumstance, competition between Lupron and Zoladex would rely even more heavily on nonprice (or "nonfinancial") forms,

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Note, however, the Dr. Hartman does implicitly render such an opinion, because his liability and damage analysis overlooks the economic consequences of the unchanged "market power" of providers in his version of the "but for" world.

[20] Deposition of Raymond Hartman, p. 862.

because the companies would have higher revenues at the current prices and thus still would want doctors to select their product over that of the competition.[21] Additional non-price competition may take the form of more advertising, support from detail personnel, educational seminars and other activities aimed at urologists and others who make the choice about which treatment to use. This could result in higher prices as less efficient forms of promotion replace the preferred way in which manufacturers compete today.

51. Note in particular that Dr. Hartman's assumption that WAC would be close to actual ASP in the but-for world —which as noted he introduces without any explicit analysis— is not consistent either with his other claims and analysis or with the actual structure of the market. This is because urologists will prefer a product with a higher WAC so long as the allowed spread is positive, because the amount the provider receives is greater, as explained earlier.

52. This analysis of the "but-for" world is based on the known economic structure of the market (especially with reference to the important role of doctors in determining market share for Lupron and Zoladex) and the empirical realities that have been observed for more than 15 years. The result shows clearly that the WAC (and AWP) would not decrease to the level of current ASP if the spread were restricted. In particular, the analysis shows that the assumptions upon which Dr. Hartman bases his damage calculations are implausible. Instead, the economic conditions would act to increase ASP until it was within the "acceptable" (under the spread restriction) range of AWP.

[21] The role of competition along non-financial dimensions is acknowledged by Dr. Rosenthal in her report (see Report of Meredith Rosenthal, December 15, 2005, ¶29).

C. CHANGES IN MEDICARE SHOW THAT DRUG REIMBURSEMENT AND OTHER PAYMENTS TO PROVIDERS ARE RELATED

53. Dr. Hartman assumes that drug prices and reimbursement provisions are independent of other financial compensation that payers give providers for the package of services associated with administration of a PAD like Zoladex. For this reason, he asserts that in the but-for world all other components of the financial arrangement between payers, patients, providers and drug manufacturers would be unchanged except that AWP (and the spread) would decline. One of the ancillary items associated with administration of Zoladex is payment for physician services. Dr. Hartman assumes that the historical arrangements between providers and payers for reimbursement of such services would be the same if the spread for reimbursement of Zoladex were lower.

54. Throughout the 1990s and 2000s, however, there has been widespread recognition that Medicare and other payers viewed the "spread" as an essential part of physician compensation. It has been widely accepted that the decision to reimburse doctors based on AWP was (at least in part) a way to compensate for inadequate reimbursement rates for physicians' services and thereby to assure that they earned a large enough return from dispensing products like Zoladex that they would continue to serve Medicare patients. Throughout the 1990s, discussion in Congress and elsewhere about changing the reimbursement formula for PADs typically acknowledged that, by itself, Medicare reimbursement for physician

services associated with administration of PADs did not provide sufficient incentive for providers to serve patients appropriately.[22]

55. Recent evidence from the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act ("Medicare Modernization Act") and the change in how Medicare reimburses providers for PADs and for Zoladex in particular shows clearly that this assumption is false. Beginning in 2001, Congress began considering changes in the allowed charges for Medicare Part B drugs, which, in 2002, were $441 for Zoladex and $627 for Lupron.[23] In 2003, the Medicare Modernization Act became law, and it mandated reduced payments for Part B drugs including Zoladex.

56. This Act also required the Secretary of Health and Human Services to revise the physician fee schedule for administration of drugs, given that in the future Medicare was going to reimburse physicians at lower rates for certain drugs. The result of this review was to increase substantially the fee paid by Medicare for administration of Zoladex. The 2002 payment had been $5.07 for the associated CPT code (the old code was 96400; the new code was G0356). This payment increased to $37.52 in 2003 and $48.54 in 2004.[24] This adjustment occurred at least in part because of recognition that, for certain specialties (including urologists), the reduction in provider revenue from lower drug reimbursements could have an adverse effect on provider income and thus on the medical care received by Medicare beneficiaries.

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[22] See Gaier Declaration for a summary of this discussion.
[23] Federal Register, Vol. 69, No. 4, 1/7/04, 1084.
[24] Ibid, p. 66406.

57. Not surprisingly, Medicare appears to have recognized that changes in drug reimbursement do not occur in a vacuum, but instead can require changes in reimbursement for other ancillary services and activities if the quality and quantity of medical care is to remain unchanged. This same principle applies to reimbursement arrangements between providers and TPPs. In Dr. Hartman's "but-for" world, in which the spread on Zoladex is reduced to 30 percent or less and ASP is unchanged, TPPs would have to increase other payments to providers to maintain the same quality of care for their clients (where quality is measured, among other things, by the size and scope of the provider network, the location in which care is provided, and the type of care provided). A proper damages analysis would take these adjustments into account, and would have to offset against any claimed reduction in payments for drugs in the but-for world the increases in other costs that would occur. Dr. Hartman failed to take these adjustments into account either qualitatively or in quantifying his estimate of damages from the AstraZeneca's alleged fraud.[25]

VIII. PULMICORT RESPULES

58. The other AstraZeneca product that Dr. Hartman claims (in his Addendum, although not in his Initial Report) was priced fraudulently and for which Class members are entitled to damages is Pulmicort Respules. With regard to this product, it is obvious that the Plaintiffs' claims, and Dr. Hartman's analysis, are

[25] In his deposition, Dr. Hartman does acknowledge the linkage between drug reimbursement amounts and other payments to doctors. In discussing the market power of doctors, such as urologists and oncologists, he says that "I mean, they [payers and providers] are also negotiating the fees, so that there are other things being negotiated. Money being paid to the provider is not just the amount on the drugs. There is fees, and there is – there is other things being negotiated." (p. 870)

completely without merit. First, the vast majority of sales of Pulmicort Respules are made through pharmacies that fill prescriptions for use by very young patients (under aged four). These are not reimbursed by Medicare. Currently, only an estimated four or five percent of Pulmicort Respules are reimbursed by Medicare.[26]

59. Second, the vast majority of Pulmicort Respules sales are made at approximately WAC – or at the list price set by AstraZeneca for this product. Because most Pulmicort Respules sales are made to patients paying cash or reimbursed by TPPs, there is no competitive incentive by pharmacies to increase "spread" for providers who prescribe the product. Finally, Dr. Hartman finds positive damages only by changing his methodology from the original yardstick method, and only by making (unwarranted) assumptions about the fraction of Pulmicort Respules' sales made on behalf of Medicare beneficiaries. When these assumptions are corrected, there are no damages associated with sales of Pulmicort Respules.

60. At his deposition, Dr. Hartman acknowledged that he had little if any knowledge of the use, competitive structure or any of the factors relevant in determining whether the type of "fraud" alleged by the Plaintiffs possibly could be relevant to pricing of Pulmicort Respules. He then admitted that, if the facts and economics of sales of Pulmicort Respules were as I describe below, then the conclusions on liability and damages presented in his Addendum would not hold.[27] Thus, even

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[26] See, Deposition of John Freeberry, October 4, 2005, p. 20.

[27] For example, Dr. Hartman acknowledged that he did not know that Pulmicort Respules was not assigned a J-Code until 2002: (Q: if you were to learn, Doctor, that Pulmicort did not have a J-Code corresponding to it in the years 2000 and 2002, this analysis damages for 2000 and 2001 would be incorrect, is that right?

the Plaintiffs' expert has concluded that there is no basis for claims that there is liability and damages from AstraZeneca's sales of Pulmicort Respules.

A. THE HISTORY OF PULMICORT RESPULES

61. Pulmicort Respules is an anti-inflammatory synthetic corticosteroid for treatment of asthma in young children (ages 12 months to eight years). The product was launched in September 2000 at a WAC of $105 (for 60 doses). Medicare did not assign a J-code for Pulmicort Respules until 2002. Because Pulmicort Respules is administered with a nebulizer – which is classified by Medicare as Durable Medical Equipment – it is reimbursed under Medicare Part B when prescribed to Medicare beneficiaries with Part B coverage.

62. Pulmicort Respules was the first inhaled corticosteroid indicated for use for children under age four. In a 1999 document, AstraZeneca identified the primary competition for Pulmicort Respules as Singulair, inhaled bronchial steroids, and various generic products, all of which competed for sales to young children. The

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A: ...If you're telling me that the criteria which I used to identify what were physician-administered drugs or reimbursed under Medicare Part B, if the claim is that in 2000/2001 they weren't, I would have to have my team go back and – and revisit those – the factual evidence and clarify whether there was something that wasn't interpreted correctly or there were some missing information. (p. 1117)). He also acknowledged that he did not know that doctors do not negotiate reimbursement for Pulmicort Respules (Q: ..to the extent that doctors are not involved in the negotiation over reimbursement rates because they don't administer Pulmicort respules, there's a division between the entity that is responsible for a prescription decision and the entity that negotiates the reimbursement with payers as to Pulmicort respules, is that right? A: That would be correct to the extent that's true. Q: Did you take that into account at all in rendering opinions with respect to Pulmicort respules in this case? A: The assumption in – built into this – into the modeling has been that the physician is the – is the entity, the provider that is primarily responsible for the negotiation. Q: And to the extent that assumption is incorrect, you would want to revisit your analysis with respect to Pulmicort, is that right? A: That's correct. (p. 1137-38))